Criteria and Standards
for
Certificate of Need
2000 Edition

Prepared by the
Health Planning ~~Commission~~ Agency

CONTENTS

GENERAL CRITERIA

CERTIFICATE OF NEED CATEGORIES

Section I Nursing Home and Hospital Facilities or Services

Section II Mental Health, Mental Retardation, and Alcohol and Drug Abuse Services

Section III Medical Equipment and Services

Section IV Home Health and Hospice Services

Section V Special Procedures

Section VI Treatment and Diagnostic Centers

PREFACE

The Tennessee Certificate of Need Program is administered by the Health ~~Facilities Commission~~ Services and Development Agency ("The Agency") under the authority of Tennessee Code Annotated Title 68, Chapter 11, Part 1, the Tennessee Health Services and Planning ~~and Resource Development Act~~ of 2002. The Department of Health, and the Department of Mental Health and Developmental Disabilities, ~~and the Division of Mental Retardation Services~~ provide~~s~~ technical support for the ~~Health Facilities Commission~~ Agency. This will be in the form of a written review and analysis of the project. It will compare these guidelines with the applicant's projections and the existing data in the service area.

The criteria and standards contained in this manual are used by certificate of need (CON) applicants and the reviewing authority to generate baseline information during the review process. The information is then used as the basis for decisions concerning certificate of need proposals.

Certificate of Need applications are reviewed by the Health ~~Facilities Commission~~ Services and Development Agency ("The Agency") in accordance with three major criteria: need, economic feasibility, and contribution to the orderly development of adequate and effective health care. The following criteria and standards do not supersede the code section in any way and are meant to provide additional guidance to assist the ~~Commission~~ Agency in its review of CON applications.

In this document, the user will find specific criteria and standards concerning the need for the facility or service in question. Please note that generic sets of criteria and standards concerning economic feasibility and the contribution to the orderly development of health care are listed on pages 8 and 9.

Types of facilities and services referred to in these guidelines were selected from appropriate sections of the Tennessee Code Annotated, Rules of the Health ~~Facilities Commission~~ Services and Development Agency ("The Agency"), Department of Health, Department of Mental Health and Developmental Disabilities, ~~Division of Mental Retardation Services,~~ and other recognized professional health organization publications.

Prospective applicants are encouraged to contact the ~~Health Facilities Commission~~ Agency staff concerning the review process before preparing an application. The staff is available to provide advice or other relevant information.

Correspondence and telephone calls should be directed to the:

Health ~~Facilities Commission~~ Services and Development Agency
~~500 James Robertson Parkway, Suite 760~~ 500 Deaderick Street, Suite 850
Nashville, TN ~~37219~~ 37243
(615) 741-2364

During the development of this document, the ~~Commission~~ Agency received advice from a number of State agencies including the Department of Mental Health and Developmental Disabilities, Division of Mental Retardation Services, and the Department of Health (Bureau of Policy Planning and Assessment, Bureau of Alcohol and Drug Abuse Services, and the Division of Health Care Facilities - Office of Health Licensure and Regulation). Other agencies involved were the Tennessee Medical Association, Tennessee Hospice Association, Tennessee Association for Home Care, and the Tennessee Perinatal Advisory Committee. The ~~Commission~~ Agency wishes to express appreciation for all assistance received.

HEALTH PLANNING ~~COMMISSION~~ AGENCY PHILOSPHY

It is the policy of the State of Tennessee that every citizen have reasonable access to mergent and primary care; that the State's health care resources are developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the State's health care industry; that every citizen can have confidence that the quality of health care is continually monitored and standards adhered to by health care providers and that the State supports the recruitment and retention of a sufficient and quality health care work force to accomplish this task, the…

The following are philosophic positions and guidelines of the Health ~~Planning Commission~~ Services and Development Agency ("The Agency") to be considered by the Health ~~Facilities Commission~~ the Agency ~~or other commissions~~ when reviewing applications for certificates of need.

1. The ~~Health Planning Commission (HPC)~~ Agency supports a philosophy that directs the delivery of health care services to the most medically appropriate, least intensive(restrictive) and most cost-effective health care settings.

2. The ~~HPC~~ Agency recognizes all institutions as equal regardless of ownership, i.e., for profit, not for profit, government, etc., but strongly favors those institutions that provide services to the elderly, categorically needy, and indigent patients. When applying any specific formula, the elderly, categorically needy, and/or indigent patients not served by the facility will be removed from that formula. For example, those providers who do not provide services to TennCare patients will subtract the appropriate TennCare population from the total population to be served before applying the formula. This pertains to all types of providers seeking a certificate of need.

3. The ~~HPC~~ Agency supports the position that every citizen, regardless of ability to pay, should have access to basic health care services, i.e., those services provided in a clinic setting or secondary hospital setting (basic inpatient care, obstetrics, primary surgical services, and emergency care).

4. The ~~HPC~~ Agency feels that preference should be given to patient accessibility, availability, and affordability needs when making a certificate of need determination of establishment, relocation, replacement, or discontinuation of health care institutions or services.

RULES
OF
THE TENNESSEE HEALTH ~~FACILITIES COMMISSION~~ Services and Development Agency
CHAPTER 0720–4
CERTIFICATE OF NEED PROGRAM–GENERAL CRITERIA
TABLE OF CONTENTS

0720—~~2~~ 4—.01 DEFINITIONS. The following terms shall have the following meanings.

(1) ***"Adult psychiatric"*** means inpatient Mental health services provided to patients over 21 years of age.

(2) ***"Ambulatory surgical treatment center"*** means any institution, place or building devoted primarily to the performance of surgical procedures on an outpatient basis.

(3) ***"Capital expenditure"*** in relation to a proposed modification, renovation, or addition to a health care institution, means an expenditure by or on behalf of a health care institution which, under generally accepted accounting principals, is not properly chargeable as an expense of operation and maintenance. Any series of expenditures, each less than the threshold, but which when taken together are in excess of the threshold, directed toward the accomplishment of a single goal or project, requires a Certificate of Need. Any series of related expenditures made over a twelve (12) month period will be presumed to be a single project.

(a) ***Modifications, additions, or renovations***. In calculating the capital expenditure for modifications, additions, or renovations "capital expenditure" is the amount per construction bid or total amount of invoices for the single project excluding major medical equipment.

(b) ***Equipment.*** The cost of major medical equipment over $1 million is not considered when determining the amount of capital expenditures for determining whether the $2 million threshold is met for a modification, addition, or renovation. The cost of all other equipment, whether fixed or moveable, is considered. The cost of major medical equipment is considered in calculating the amount of the examination fee. The cost for such fixed and moveable equipment includes, but is not necessarily limited to, taxes, government fees, assessments, and any other fees, assessments or charges directly associated with the acquisition of the equipment.

(c) ***Lease, loan, or gift***. In the case of a lease, loan, or gift, the "cost" is the fair market value of the equipment.

(4) ***"Certification period"*** means the period of time beginning on the date of issuance of a certificate of need and ending on the expiration date of a certificate of need, as established by statute, rule, or order of the ~~Commission~~ Agency.

(5) ***"Change of location"*** means a change of the specific location of an existing institution, facility, service, or piece of major medical equipment, in part or in its entirety. The relocation of a parent office of a home health agency within the same county is not considered a change of location of a health care institution. The following activities involving a home health agency are a change of location of a health care institution, and require a certificate of need:

(a) The addition of one or more counties to the licensed service-area of a home health agency;

(b) The change of location of a parent office to a different county;

(c) The establishment of a "sub-unit" of a home health agency.

(6) ***"Child and adolescent psychiatric"*** means inpatient Mental health services provided to patients up to and including 21 years of age.

(7) ***"Expiration date"*** is the date upon which a certificate of need expires and becomes null and void. The expiration date may be established by statute, by rule, or by order of the ~~Commission~~ Agency.

(8) ***"Home health service"*** is as defined in *T.C.A.* Title 68, Chapter 11, Part 2.

(9) ***"Hospital"*** is as defined in *T.C.A.* Title 68, Chapter 11, Part 2.

(10) ***"Hospital projects"*** as used in *T.C.A. §68-11-108(c)* to determine the period of validity, is limited to hospital projects involving capital costs expenditures of $2 million or greater.

(11) ***"Long-term categories"*** includes nursing home services, regardless of the length of stay, and any other health service which is intended or reasonably expected to result in an average length of stay of 2l days or longer.

(12) ***"Major medical equipment" — "Cost."***

(a) As used in *T.C.A. §68-11-106(a)(6).* "major medical equipment" means any single item of equipment. or a series of components with related functions, within the definition and cost threshold set forth the referenced statute.

(b) The cost of major medical equipment includes all costs, expenditures, charges, fees and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following:

1. maintenance agreements, covering the expected useful life of the equipment;

2. federal, state, and local taxes and other government assessments; and

3. installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding.

(c) Any individual components or a piece of medical equipment with related functions, which are purchased over a 12 month period shall be considered toward the cost of the piece of major medical equipment.

(d) If the acquisition is by lease, the cost is either the fair market value of the equipment, or the total amount of the lease payments, whichever is greater

(13) ***"Mental health hospital"*** means an inpatient facility which is held out to the public as a hospital, and in connection with the services of a physician, offers diagnosis, treatment, and care to Mentally ill individuals on a comprehensive inpatient basis, as licensed by the Department of Mental Health/Mental Retardation.

(14) ***"Mental health residential treatment facility"*** means a community-based or hospital affiliated facility or unit that offers 24-hour residential care, as well as, a treatment and rehabilitation component for Mentally ill individuals. The focus of the program may be on short-term crisis stabilization or on longterm rehabilitation that includes training in community living skills, vocational skills, and/or socialization. The staff includes direct-care staff as well as Mental health treatment staff . The facility offers relatively high intensity treatment program(s), and requires a relatively high level of supervision for the residents/patients. The population served by such facilities may be at a high risk of hospitalization or institutionalization because of the pervasive nature of their problems.

(15) ***"Mental retardation institutional habilitation facility"*** means a facility which offers on a regular basis health related services to individuals with Mental retardation who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but, because of physical or Mental condition require residential care and services (more than room and board) and involves health related care under the supervision of a physician. Such a facility also offers an intensive program of habilitative services, as licensed by the Department of Mental Health/Mental Retardation.

(16) ***"Neonatal intensive care nursery"*** means a special care unit staffed and equipped to provide professional intensive treatment for the care of seriously ill newborn infants and high-risk newborn infants, staffed by a neonatologist and specialized nurses and in which bassinets are used as licensed beds.

(17) ***"Not directly related to patient care"*** may include the following types of single, isolated expenditures:
(a) Telephone systems;
(b) Non-clinical data processing systems;
(c) Heating and/or air conditioning systems;
(d) Energy conservation devices;
(e) Parking facilities;
(f) Roof repairs;
(g) Medical office buildings;
(h) Warehouses; and
(i) Cafeterias.

(18) ***"Nursing home"*** is as defined in *T.C.A.* Title 68. Chapter 11, Part 2.

(19) ***"Outpatient diagnostic center"*** means any agency, institution, facility or place which primarily performs diagnostic procedures on an outpatient basis only.

(20) ***"Person"*** where the context requires, may refer to any natural person, legal entity, facility, or institution.

(21) ***"Recuperation center"*** is as defined in *T.C.A.* Title 68, Chapter 11, Part 2.

(22) ***"Rehabilitation"*** means an inpatient health care service provided with the purpose of assisting in the restoration or improvement of physical functions of physically disabled persons.

(23) ***"Residential hospice"*** is as defined in *T.C.A.* Title 68. Chapter 11, Part 2.

(24) ***"Service area"*** means the county or counties representing a reasonable area in which a health care institution intends to provide services and in which the majority of its service recipients reside.

(25) ***"Sub-unit"*** means a semi-autonomous home health agency, which serves patients in a geographic area different from that of its parent home health agency. The sub-unit is located at such a distance from the parent home health agency, so as to require a separate license by the Department of Health.

(26) ***"Substantive amendment"*** as used in *T.C.A. §68—11—106(d)(7)* means any amendment which has the effect of increasing the number of beds, square footage, cost, or other elements which are reasonably considered to be integral components of the application. A reduction of the above referenced components may be considered a substantive amendment if the amendment and supporting documentation are not received by the staff and ~~Commission~~ Agency in a timely manner, necessary to allow the ~~Commission~~ Agency to make an informed decision. Nothing in this rule shall be interpreted as limiting the ~~Commission's~~ Agency's authority to approve or deny all or part of any given application.

Authority: *T.C.A. §§ 68—11—105(2) (as amended, P.C. 120, Acts of 1993, Section 3), 4—5—202.* ***Administrative History****: (For history prior to October, 1987,see page 1). Repeal and new rule filed September 15, 1987, effective October 30, 1987. Amendment filed August 30, 1988; effective October 14, 1988. Repeal and new rule filed November 16, 1993, effective January 30, 1994. Amendment filed September 12, 1994; effective January 27, 1995.*

0720–4–.0~~1~~2 GENERAL CRITERIA FOR CERTIFICATE OF NEED. The ~~Commission~~ Agency will consider the following general criteria in determining whether an application for a certificate of need should be granted:

(1) Need. The health care needed in the area to be served may be evaluated upon the following factors:

(a) The relationship of the proposal to any existing applicable plans;

(b) The population served by the proposal;

(c) The existing or certified services or institutions in the area;

(d) The reasonableness of the service area;

(e) The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, and low-income groups;

(f) Comparison of utilization/occupancy trends and services offered by other area providers;

(g)The extent to which Medicare, TennCare/Medicaid, and ~~medically indigent patients~~ low-income groups will be served by the project.

(2) Economic Factors. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors:

(a) Whether adequate funds are available to the applicant to complete the project;

(b) The reasonableness of the proposed project costs;

(c) Anticipated revenue from the proposed project and the impact on existing patient charges;

(d) Participation in state/federal revenue programs;

(e) Alternatives considered;

(f) The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.

(3) Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services. The contribution which the proposed project will make to the orderly development of an adequate and effective health care system may be evaluated upon the following factors:

(a) Conforming to the goals for quality health care for Tennesseans as set forth in the State Health Plan outlined by the State Health Planning and Advisory Board.

(~~a~~b)The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, affiliation of the project with health professional schools);

(~~b~~c)The positive or negative effects attributed to duplication or competition;

(~~c~~d)The availability and accessibility of human resources required by the proposal, including consumers and related providers;

(~~d~~e)The quality of the proposed project in relation to applicable governmental or professional standards.

(4) Applications for Change of Site. When considering a certificate of need application which is limited to a request for a change of site for a proposed new health care institution, the ~~Commission~~ Agency may consider, in addition to the foregoing factors, the following factors:

(a) *Need*. The applicant should show the proposed new site will serve the health care needs in the area to be served at least as well as the original site. The applicant should show that there is some significant legal, financial, or practical need to change the proposed new site.

(b) *Economic factors*. The applicant should show that the proposed new site would be at least as economically beneficial to the population to be served as the original site.

(c) *Contribution to the orderly development of health care facilities and/or services*. The applicant should address any potential delays that would be caused by the proposed change of site, and show that any such delays are outweighed by the benefit that will be gained from the change of site by the population to be served.

Authority: T.C.A. §§68–11–105(2) and 68-11-108(b).

Comment: This has changed.

ECONOMIC FACTORS AND CONTRIBUTIONS TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

(Generic Sets of Criteria Which May Be Applied to all Applications for Certificate of Need)

A. ECONOMIC FACTORS

1. Immediate financial feasibility:

   a. The cost per square foot of new construction should be reasonable in relation to similar facilities in the state~~;~~ as compared to cost data available to the Agency;

   b. The financing mechanism should be structured to assure that funds to develop the facility will be available on reasonable terms~~;~~ as comparable to financing of similar types of facilities;

   c. The business plans for the facility will take into consideration the special needs of the service area population, including the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. The ~~HFC~~ Agency will take specific note of these considerations when making their certificateof need determinations;

   d. The proposed contracted charges should be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas;

   e. Staff salaries should be reasonable in comparison with prevailing wage patterns in the area.

2. Long term financial feasibility:

   a. The projected utilization rates should be sufficient to maintain cost-effectiveness;

   b. The projected cash flow should ensure financial viability within two years and evidence should be shown that sufficient cash flow is available until that point is reached so as not to threaten the long term financial viability of the facility.

3. Consideration of more cost-effective alternatives:

   a. The existence of superior alternatives in terms of costs, efficiency, and efficacy should be identified. If development of such alternatives is not practicable, the applicant should justify why not;

   b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

B. CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. Availability of appropriate professional staff:

   a. All licensing certifications as required by the State of Tennessee for professional staff shall be met. These include, without limitation, regulations concerning physician credentialing, admission privileges, ~~quality assurance policies and programs, utilization review policies and programs,~~ performance improvement evaluations, record keeping, and staff education.

   b. The applicant should document the availability of adequate professional staff, as per licensing requirements, to deliver all designated services in the proposal.

2. Licensure, Accreditation, and Certification:

   a. All licensed health care facilities and services shall comply with licensure requirements of the Department of Health~~,~~ and the Department of Mental Health and Developmental Disabilities~~, and the Division of Mental Retardation Services~~.

   b. An existing provider must document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction.

   c. It will be deemed to be a positive factor if the applicant seeks certification to participate in both the Medicare and TennCare programs, so as to afford access for those populations.

3. Consideration of Alternatives:

   The applicant's alternatives to the proposed project should indicate logical reasons as to why they were adopted or rejected.

4. Effect on Existing Providers:

   The applicant should describe the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

5. Data Collection:

   The applicant should state in the proposal that it will, if approved, provide the ~~Tennessee Health Facilities Commission and/or the reviewing agency~~ Agency through the Department of Health and/or the Department of Mental Health and Developmental Disabilities information concerning the number of patients treated, the number and type of procedures performed, and other data as required~~.~~ in the joint annual report.